No. 78-65

In the Supreme Court of the United States

OCTOBER TERM, 1978

INDEPENDENT COSMETIC MANUFACTURERS AND DISTRIBUTORS, INC., PETITIONER

v.

THE UNITED STATES DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE, ET AL.

INDEPENDENT COSMETIC MANUFACTURERS AND DISTRIBUTORS, INC., PETITIONER

v.

JOSEPH A. CALIFANO, JR., SECRETARY OF HEALTH, EDUCATION, AND WELFARE, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

BRIEF FOR THE RESPONDENTS IN OPPOSITION

WADE H. MCCREE, JR.,
Solicitor General,

JOHN H. SHENEFIELD,
Assistant Attorney General,

JOHN J. POWERS, III,
FREDERIC FREILICHER,
Attorneys,
Department of Justice,
Washington, D.C. 20530.

RICHARD M. COOPER,
Chief Counsel,

DONALD O. BEERS,
Assistant Chief Counsel
for Enforcement,
Food and Drug Administration,
Department of Health, Education,
and Welfare,
Rockville, Maryland 20857.

INDEX

CITATIONS

Cases:

Statutes, rule and regulations:

In the Supreme Court of the United States

OCTOBER TERM, 1978

No. 78-65

INDEPENDENT COSMETIC MANUFACTURERS AND DISTRIBUTORS, INC., PETITIONER

v.

THE UNITED STATES DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE, ET AL.

INDEPENDENT COSMETIC MANUFACTURERS AND DISTRIBUTORS, INC., PETITIONER

v.

JOSEPH A. CALIFANO, JR., SECRETARY OF HEALTH, EDUCATION, AND WELFARE, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

BRIEF FOR THE RESPONDENTS IN OPPOSITION

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 4a-66a) is reported at 574 F.2d 553. The decision of the district court (Pet. App. 1a) is not reported.

JURISDICTION

The judgments of the court of appeals (Pet. App. 2a-3a) were originally entered on January 27, 1977, and were re-entered (Pet. App. 5a) on February 13, 1978. A timely petition for rehearing was denied by that court on April 11, 1978 (Pet. App. 67a). The petition for writ of certiorari was filed on July 10, 1978. The jurisdiction of the Court is invoked under 28 U.S.C. 1254(1).

QUESTIONS PRESENTED

1. Whether the district court had concurrent jurisdiction to review regulations promulgated by the Commissioner of the Food and Drug Administration (FDA) when review in the court of appeals is specifically authorized by statute.

2. Whether petitioner's petition for review by the court of appeals of an FDA regulation requiring ingredient labeling on cosmetics was untimely under 21 U.S.C. 371(f), when it was filed more than one and one-half years after the regulation was promulgated.

3. Whether the court of appeals correctly found that petitioner was not prejudiced by the procedures followed by the Commissioner in promulgating the basic ingredient labeling regulation and amendments to it.

STATEMENT

1. The Fair Packaging and Labeling Act (FPLA), 15 U.S.C. 1451 *et seq.*, grants the Secretary of

Health, Education, and Welfare authority to promulgate regulations establishing labeling or packaging requirements or prohibitions whenever he determines that such regulations "are necessary to prevent the deception of consumers or to facilitate value comparisons as to any consumer commodity * * *."

On February 7, 1973, the Commissioner of Food and Drugs [1] filed a notice of proposed rulemaking on a regulation requiring ingredient labeling, in order of predominance, on all cosmetics (38 Fed. Reg. 3523-3525). After receipt of 291 comments from interested parties,[2] the Commissioner, on October 17, 1973,

---

[1] The Secretary's authority under the FPLA has been delegated to the Commissioner. 21 C.F.R. 5.1.

[2] Several of those commenting contended that the Commissioner did not have authority to establish ingredient labeling across the board, but was required to promulgate regulations on a commodity-by-commodity basis. The Commissioner concluded, however, that the FPLA contained ample authority to promulgate the regulation since all cosmetics could be considered a single commodity (38 Fed. Reg. 28912). He also observed that effective relief in this instance could be obtained with a comprehensive order governing all cosmetics and that cosmetic ingredient labeling was necessary to prevent deception of consumers and to facilitate value comparisons (38 Fed. Reg. 28912). In response to certain comments, the Commissioner included in the final regulation a procedure to facilitate the preservation of trade secrets, and further modified the proposed regulation in the following ways: (1) to permit placement of the ingredient statement on any appropriate information panel, rather than just on the principal display panel; (2) to recognize the Cosmetic, Toiletry and Fragrance Association Cosmetic Ingredient Dictionary as the controlling source for the ingredient name to be used in label declaration; and (3) to exempt from the label declara-

published the regulation in final form, to be incorporated in the FDA regulations as 21 C.F.R. 701.3 (38 Fed. Reg. 28912-28914). The regulation (hereinafter the October 1973 regulation) was made applicable to all cosmetic labels ordered after March 31, 1974, and to all cosmetic products labeled after March 31, 1975 (38 Fed. Reg. 28914). Those filing objections were required to do so within 30 days.[3] Although 13 persons filed objections and four of them requested a hearing, all the objections were narrowly drawn [4] and none made a general challenge to the ingredient labeling requirement as such (39 Fed. Reg. 27181). Petitioner, Independent Cosmetic Manufacturers and Distributors, Inc., did not file comments concerning the proposed regulation or objections to the regulation as published in final form on October 17, 1973.

tion requirement the ingredients in each fragrance and flavor, as well as in various "bases" such as those used in shampoo concentrates (38 Fed. Reg. 28912-28913).

[3] Under 21 U.S.C. 371(e)(2), objections to an order involving the issuance of a regulation must be filed "[o]n or before the thirtieth day after the date" on which the order is made public.

[4] The requests for a hearing involved only three aspects of the regulation: (1) the declaration of each ingredient in a color; (2) the labeling of small packages held in compartmental trays or racks; and (3) the time for compliance with the labeling requirements (40 Fed. Reg. 8922) (R. 546-551, 553, 560-564, 580-583, 587-589). The other objections, on which a hearing was not requested, concerned the following matters: (1) the listing of an ingredient substitute for another in short supply (R. 585-586); (2) the listing of a flavor or fragrance by words describing the flavor or fragrance rather than by the ingredients therein (R. 558-559); (3) the 1/16th-inch requirement with respect to the minimum-size type for listing ingredients (R. 541-542); (4) the use of the phrase "and other ingredients" where an ingredient is exempted from public disclosure (R. 539-540); and (5) the disclosure of specialty blends and color blends (R. 547-548).

After informal discussions with the objectors and others (40 Fed. Reg. 8918), the Commissioner, on July 25, 1974, announced the availability to the public of a draft order that "meets the objections [to the October 1973 order] and eliminates any need for a public hearing." 39 Fed. Reg. 27181. Further comments and discussion were solicited. *Ibid.* Petitioner reviewed the draft order, submitted comments, and twice met with FDA officials to discuss them (R. 740, 783, 895, 962, 964, 982).[5]

On March 3, 1975, the Commissioner published an order providing limited exemptions and supplemental procedures for listing certain ingredients (40 Fed. Reg. 8918-8924) (hereinafter the March 1975 amendments). These were to be in addition to the "basic provisions requiring cosmetic ingredient labeling" in the October 1973 regulation (40 Fed. Reg. 8921).[6]

[5] "R." refers to the agency record that was filed in the court of appeals in No. 75-1845, the proceeding on the petition to review (see page 9, *infra*).

[6] For example, the basic regulation required that all ingredients be listed in descending order of predominance. 21 C.F.R. 701.3(a); 38 Fed. Reg. 28913. Under the March 1975 amendments, ingredients other than color additives present at a concentration of less than one percent could be listed at the end in any order, and this could be followed by a listing

In a separate independent order issued on March 3, 1975 (40 Fed. Reg. 8924-8926) the Commissioner disposed of the objections filed with respect to the October 1973 regulation. He found no merit in most of the objections (40 Fed. Reg. 8924-8925); but he stayed the operation of, and directed a hearing on, the requirement that each color ingredient be declared, and on the issue whether to provide for off-package labeling for small cosmetic items in compartmented trays or racks (40 Fed. Reg. 8925). In response to the objections asking that the time for compliance be lengthened, the Commissioner extended the effective date of the regulations to March 3, 1976, for all labels ordered, and to September 3, 1976, for all cosmetic products labeled. *Ibid.* Thereafter, the four objectors who had requested a hearing withdrew their objections. 40 Fed. Reg. 23460. Accordingly, on May 30, 1975, the Commissioner terminated the partial stay. *Ibid.* The regulation is now in effect. 21 C.F.R. 701.3.

2. On April 1, 1975, petitioner filed papers which purported to be objections to the March 1975 amendments (R. 1079). The principal thrust of petitioner's objections, however, was that petitioner was "[i]n general * * * totally" opposed "to the concept of ingredient labeling on cosmetics" (R. 1079). Petitioner argued that ingredient labeling would enable competitors to learn cosmetic formulas and would also

---

of color additives also without respect to predominance. 21 C.F.R. 701.3(f); 40 Fed. Reg. 8919.

involve "great cost" for label changes (R. 1079-1080). Petitioner challenged 21 C.F.R. 701.3 in its "entirety" as unnecessary to prevent consumer deception or to facilitate value comparison (R. 1080-1081). Petitioner also objected to the March 3, 1975, amendments on the general ground that they were "arbitrary and unreasonably onerous" (R. 1081-1082). Petitioner then proceeded to propose as an "alternative" that ingredients be listed alphabetically or that only known allergens be listed (R. 1082-1083).[7] Petitioner demanded a hearing on all its objections (R. 1087).

The Commissioner rejected petitioner's general objection to ingredient labeling on the ground that this issue was raised by the October 1973 order and that petitioner's April 1975 objection was therefore untimely. 40 Fed. Reg. 23458. He also rejected petitioner's objections dealing with the March 1975 amendment, concluding that these objections did not raise factual issues warranting a hearing but were in fact requests "that additional exemptions be granted or alternative methods of labeling be permitted." *Id.* at 23459. Under the Act, the proper procedure for proposing additional exemptions was not, the Commissioner stated, to file "objection[s] to ex-

---

[7] Petitioner also objected to (1) the "scrambling" only of those non-color ingredients below the 1% level, (2) the limitation of "off-package" labeling to tightly compartmented trays or racks, and (3) the restriction on the option of placing a "new ingredient" list inside the carton to products with ingredient changes resulting from ingredient shortages (R. 1084-1087).

emptions granted," but rather to file "a petition to amend the regulation imposing the requirement." *Ibid.*[8]

3. On August 27, 1975, petitioner filed suit in the United States District Court for the District of Columbia, requesting that the court declare the ingredient labeling regulation unlawful and enjoin the Commissioner from enforcing the regulation (A. 13).[9] Petitioner alleged that the basic regulation was unlawful under the FPLA for the following reasons: (1) the FPLA requires that ingredient labeling be done on a commodity-by-commodity basis and cosmetics are not a single commodity; (2) there was not an adequate determination, as required by the FPLA, that the regulation was necessary to prevent deception of consumers or to facilitate value comparisons; and (3) the regulation would, contrary to provisions of the FPLA, require the divulgence of trade secrets (A. 8-10). The complaint also alleged various procedural irregularities including, among others, (1) the failure to hold a hearing on "the basic issues raised" by the regulation, (2) the failure to

[8] The Commissioner set down for hearing the question whether it is reasonable to establish a level of concentration (in this case, 1%) below which cosmetic ingredients need not be listed in descending order of predominance. He stayed the pertinent parts of the regulation (21 C.F.R. 701.3(f)(1) and (2)) pending the outcome of the hearing. 40 Fed. Reg. 23458.

[9] "A." refers to the abbreviated joint appendix to the briefs filed in the court of appeals.

publish the proposed amendments for comment (A. 10-13). The complaint was dismissed by the district court for want of subject matter jurisdiction (Pet. App. 1a).

On August 27, 1975, petitioner also filed a petition for review of the regulation in the United States Court of Appeals for the District of Columbia Circuit on the same theories it advanced in the district court (Pet. App. 12a-18a). The petition was consolidated with petitioner's appeal from the district court decision (Pet. App. 5a-6a).

The court of appeals affirmed the district court. The majority observed that judicial review provisions of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 371(f), made applicable to FPLA regulations by 15 U.S.C. 1455(a), provided for exclusive jurisdiction in the court of appeals, absent agency action which is *ultra vires* (Pet. App. 6a). It concluded that the conduct of the Commissioner was not *ultra vires* because there was no showing of a "patent violation" of agency authority (Pet. App. 7a). The court of appeals also denied the petition for review. It held that the August 1975 petition for review was untimely because it was not filed within 90 days of the October 1973 order promulgating the regulation, as required by 21 U.S.C. 371(f)(1). Regarding petitioner's claim that its failure to file its petition attacking the basic regulation within the prescribed 90-day period was attributable to procedural irregularities occurring in the promulgation and amendment of the regulation, the court of appeals found

(Pet. App. 15a-17a) that the alleged procedural irregularities related to matters having nothing to do with petitioner's basic challenge to the regulation. The court thus concluded (Pet. App. 16a-17a) that if there were procedural infirmities, petitioner was not prejudiced by them.[10]

ARGUMENT

The decision of the court of appeals is correct and it does not conflict with any decision of this Court or any other court of appeals. Accordingly, it does not warrant further review.

1. Petitioner contends (Pet. 11-17) that the district court had concurrent jurisdiction, pursuant to 21 U.S.C. 371(f)(6), to review the regulation promulgated by the Commissioner. However, as the court of appeals properly concluded, the regulations challenged by petitioner in the district court could have been challenged by a timely petition for review in an appropriate United States Court of Appeals. 15 U.S.C. 1455(a); 21 U.S.C. 371(f). Where Congress has expressly provided "a procedure for judicial review of administrative action, that procedure is the exclusive means of review unless, because of some extraordinary circumstances, the procedure fails

[10] Circuit Judge Wilkey, dissenting, was of the view that the FPLA conferred jurisdiction on the district court and that the petition for review in the court of appeals was timely because the October 1973 regulation was not a final agency action that would warrant judicial review (Pet. App. 19a-66a).

to provide an adequate remedy" (Pet. App. 6a).[11] See also *Nader* v. *Volpe*, 466 F.2d 261, 271 (D.C. Cir. 1972). This Court's decision in *Abbott Laboratories* v. *Gardner*, 387 U.S. 136 (1967), relied upon by petitioners (Pet. 12-13), supports this result. *Abbott* involved the question whether there could be pre-enforcement judicial review of the Commissioner's action in promulgating a regulation not subject to the special statutory review procedure in 21 U.S.C. 371(e)-(g) or to any other statute expressly providing for judicial review. 387 U.S. at 146-147. Since there was no other adequate remedy, the Court, relying in part upon the savings clause in 21 U.S.C. 371(f)(6), cited by petitioners in this case, held that the district court had jurisdiction to afford equitable relief. 387 U.S. at 140-144. The Court was, however, careful to distinguish the regulation before it from one, like the regulation at issue in this case, that is subject to the special review provisions of 21 U.S.C. 371(e)-(g). 387 U.S. at 145-146.[12] See *Whitney National Bank* v. *Bank of New Orleans and Trust*

[11] As the court of appeals noted (Pet. App. 9a), any other rule would permit an aggrieved party which had slept on its rights to bypass the 90-day time limit within which it must file a petition for review in the court of appeals, pursuant to 21 U.S.C. 371(f)(1), as petitioner tried to do in this case (see pages 12-13, *infra*).

[12] The Court quoted with approval the Notes of the Advisory Committee on the Federal Rules of Civil Procedure, Rule 57: "A declaration [by the district court] may not be rendered if a special statutory proceeding has been provided for the adjudication of some special type of case * * *." 387 U.S. at 146 n.13.

Company, 379 U.S. 411, 421-422 (1965). Thus, since judicial review by a court of appeals was available, the district court lacked jurisdiction, absent "extraordinary circumstances" not present here (Pet. App. 6a), to hear this case.

2. Petitioner contends (Pet. 20-23) that the order promulgating the basic regulation in October 1973 was not a "final order" from which an appeal could be taken because the Commissioner later amended the basic regulation on May 30, 1975. It thus argues that, notwithstanding the requirement in 21 U.S.C. 371(f)(1) that a petition for review of an agency order promulgating a regulation be filed within 90 days of the "day such order is issued," its review petition was timely because it was filed within 90 days of the date the amendments were promulgated.

The court of appeals (Pet. App. 14a-15a) properly rejected this contention. Petitioner's challenge is to the legality of the basic regulation adopted in the October 1973 order. That regulation was promulgated in final form, after comment, with an effective date. The impact upon petitioner's members was direct and immediate in that they were compelled to make immediate preparations for label changes. Nothing more is required to make an order final and thus reviewable. *Abbott Laboratories* v. *Gardner*, *supra*, 387 U.S. at 148-153; *Port of Boston Marine Terminal Association* v. *Rederiaktiebolaget Transatlantic*, 400 U.S. 62, 71 (1970).

That the effective date on the regulation was postponed, or that there were later amendments provid-

ing limited exceptions to the basic regulation, does not make the October 1973 order any less final for judicial review purposes.[13] At the very least, the October 1973 regulation represented the "actual application of the [ingredient-labeling] plan in its initial stage." *Panhandle Eastern Pipe Line Co.* v. *Public Service Commission of Indiana*, 332 U.S. 507, 512 (1947). In such circumstances, a party need not wait for a later order before contesting the action already taken. *Ibid.* Had petitioner filed a timely petition for review in the court of appeals, the court would have considered petitioner's challenge to the October 1973 regulation on its merits, as it has reviewed appeals from agency actions whose finality was arguably far less clear than that here. *Independent Bankers Association of America* v. *Smith*, 534 F.2d 921, 926-930 (D.C. Cir. 1976); *Goodman* v. *Public Service Commission*, 467 F.2d 375, 377-378 (D.C. Cir. 1972); *Environmental Defense Fund, Inc.* v. *Ruckelshaus*, 439 F.2d 584, 589 and n. 8 (D.C. Cir. 1971).

3. Petitioner contends (Pet. 17-20) that various alleged procedural errors effectively precluded it from participating in the promulgation of the regulation and "eclipsed" its right to judicial review. These

[13] If a party were permitted to challenge the legal basis for an agency regulation years after it was promulgated in final form simply because amendments to the regulation had been entertained, the agency might well be discouraged from considering and making salutary changes or amendments to the basic regulations. It would also be unfair to the agency and to those regulated who have acted in reliance on the absence of any initial challenge to the legality of a regulation.

contentions were carefully considered and properly rejected by the court of appeals (Pet. App. 15a-17a).

The procedures followed by the Commissioner in this case were "at least in part, invited by the objectors" to the regulation (Pet. App. 7a), and those procedures ultimately resulted in the withdrawal of the objections. In any event, none of the alleged errors prejudiced petitioner's ability to seek judicial review. Thus, the Commissioner's failure to hold a hearing on objections to the October 1973 regulation could not have prejudiced petitioner, because the arguments it subsequently raised were unrelated to the narrow issues raised in the objections.[14] For the same reason, petitioner was not prejudiced by the Commissioner's failure to publish promptly a notice indicating what parts of the October 1973 order had been stayed by the filing of objections. The provision for a stay in 21 U.S.C. 371(e)(2) is, as the court of appeals observed (Pet. App. 17a), independent of the requirement in Section 371(f)(1) that petitions for review be filed within 90 days after an order issuing a regulation is issued.

Nor was petitioner prejudiced by the Commissioner's failure to publish the proposed amendments on July 24, 1974, prior to their promulgation in final form on March 3, 1975 (Pet. 18). Those amendments

[14] The objectors were later able to resolve their differences with the Commissioner and withdrew their request for a hearing (see page 6, *supra*). Under the statute, the Commissioner is required to hold a hearing only where there is a request for one. 21 U.S.C. 371(e)(3).

were unrelated to the basic labeling requirement announced in the October 1973 regulations to which petitioner now belatedly objects. In any event, the record reflects that petitioner was able to review the proposed amendments, comment upon them, confer with FDA officials concerning them, and object to them (page 5, *supra*).

In sum, petitioner slept on its rights, neither filing objections to the October 1973 regulation nor filing a petition for review within 90 days after its promulgation. Complaining of unrelated procedural irregularities, petitioner now seeks to circumvent statutory requirements for review. The court of appeals properly declined to create a special exemption (Pet. App. 17a).

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

WADE H. MCCREE, JR.,
Solicitor General.

JOHN H. SHENEFIELD,
Assistant Attorney General.

JOHN J. POWERS, III,
FREDERIC FREILICHER,
Attorneys.

RICHARD M. COOPER,
Chief Counsel,

DONALD O. BEERS,
Assistant Chief Counsel
for Enforcement,
Food and Drug Administration,
Department of Health, Education,
and Welfare.

SEPTEMBER 1978.

☆ U. S. GOVERNMENT PRINTING OFFICE: 1978 273541 122